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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,313	11/16/1999	ALLAN SVENDSEN	5709.200-US	4161
25908 7590 01/05/2004				
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				
EXAMINER HUTSON, RICHARD G				
ART UNIT		PAPER NUMBER		
1652				

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

SM

Application No.

09/441,313

Applicant(s)

SVENDSEN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants cancellation of claims 1-61 and the addition of new claims 62-78 in the paper of 8/19/2003 is acknowledged. Claims 62-76 are at issue and are present for examination.

Applicants' arguments filed on 8/19/2003 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

Applicants amendment of the specification, to overcome the previous rejection is acknowledged. It is further pointed out to applicants that while their amendment moves to overcome the previous objection it may still be considered somewhat confusing in the recitation "may also be separated as follows, i.e., meaning the same as the plus sign Asp30Ala/Ser34Glu or N30A/S34E" as applicants have not maintained consistency with the first part of applicants amendment which recites "Ala30Asp + Glu34Ser or A30NQ+E34S"

Appropriate correction is required.

Claim Objections

Claims 63, 69 and 76-78 are objected to because of the following informalities:

Claim 63 recites "...alpha-amylase that that..."

Claims 63, 69 and 76-78 each are drawn to the DNAS sequence of claim 62 or 73-78, and each further limit the claim from which they depend by limiting the claimed DNA such that it must comprise an additional mutation then that originally stipulated in the claim from which they depend. It is suggested that if this is in fact applicants intentions, that applicants amend these claims in a similar fashion as claim 70, by including the recitation "... of claim 62, **further** ..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA sequence encoding an alpha-amylase comprising the amino acid sequence of SEQ ID NO: 4 with an alteration at S356 or E376, does not reasonably provide enablement for any DNA sequence encoding an alpha-amylase, said alpha amylase having an amino acid sequence which is at least 70% identical to SEQ ID NO: 4 and having an alteration at a position corresponding to S356 or E376, using SEQ ID NO: 4 for numbering. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 42 and 44-61. In response to this rejection applicants have cancelled claims 42 and 44-61 and added new claims 62-78 corresponding to the subject matter found in previous claims 42 and 44-61.

Applicants traverse this rejection on the basis that applicants have amended the claims such that the parent of the variant alpha-amylase is a "Termamyl-like alpha amylase" having an amino acid sequence at least 70% identical to SEQ ID NO: 4 and that applying the Wands factors, it is clear that the claimed invention is enabled commensurate with the scope of the claims.

Applicants argue that the test for determining enablement is not whether any experimentation is required, but rather whether undue experimentation is required and that such permits a considerable amount of testing. Applicants argue that the experimentation that would be required by the artisan practicing the present invention is clearly not undue, but merely routine. Applicants further submit that applicants have provided clear and sufficient guidance in the specification as well as working examples. Applicants conclude that given the above in view of the additional guidance provided by the prior art, one of skill in the art would be allowed to prepare the claimed variants.

Applicants argument is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a variant alpha-amylase) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of

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variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish:: (A) regions of the protein structure which may be modified without effecting alpha-amylase activity; (B) the general tolerance of alpha-amylases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of any alpha-amylase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA sequence encoding any alpha-amylase, said alpha amylase having an amino acid sequence which is at least 70% identical to SEQ ID NO: 4 and having an alteration at a position corresponding to S356 or K376. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly,

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extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'R. G. Hutson', followed by a horizontal line.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
12/22/2003